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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,438	11/20/2001	William Stefan Bess	5724-03-EJF	3857

7590

03/04/2002

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EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 03/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/996,438

Applicant(s)

Nichols et al.

Examiner

First Last

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1234

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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## **DETAILED ACTION**

### ***Status of Claims***

1. Claim 1 is pending.
2. Claim 1 is rejected.

### ***Information Disclosure Statement***

3. The information disclosure statements filed on September 8, 1999 and December 27, 1999 have been reviewed and considered, see enclosed copy of PTO FORM 1449.

### ***Specification***

4. It is noted that page 14 of the instant specification is not present in this application. The examiner respectfully requests a copy of this page with a response to this Office Action.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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6. Claim 1 is rejected under 35 U.S.C. 102(a) as being clearly anticipated by Nichols et al. of WO 97/37689. Nichols et al. teach of a composition containing a sympathomimetic amine with other compounds which make it difficult or essentially infeasible to synthesize illegal drugs from the sympathomimetic amine compounds, (see page 4, lines 1-23).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hanna et al. of U.S. Patent No. 4,601,894 possessing an issue date of July 22, 1986. Hanna et al. disclose of a pharmaceutical composition containing pseudoephedrine sulfate and ethylcellulose, (see column 1, lines 50-57 and column 2, lines 43-46).

9. Keown et al. of WO 95/11034 which has a publication date of April 27, 1995. Keown et al. teach of a pharmaceutical composition containing a sympathomimetic agent, such as ephedrine, and a mineral cation salt, such as chromium, (see abstract).

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nakamoto et al. of U.S. Patent No. 3,773,920 possessing an issue date of November 20, 1973. Nakamoto et al. teach of the following pharmaceutical composition of phenylephrine and the copolymer of methyl cellulose.

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***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keown et al. of WO 95/11034 which has a publication date of April 27, 1995. Keown et al. teach of a pharmaceutical composition containing a sympathomimetic agent, such as ephedrine, and a mineral cation salt, such as chromium, (see abstract). Applicants attempt to limit the instant composition claims with functional language regarding the intended use of the compound, such as in the case with the combination inhibitor of a transition metal, like chromium. The prior art reference of Keown et al. does teach of the instantly claimed composition. The selection of a known material based on suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297

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(1945). Note that composition claims are not deemed to be limited by “intended use”, see In re Hack 114 USPQ 161.

14. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamoto et al. of U.S. Patent No. 3,773,920 possessing an issue date of November 20, 1973. Nakamoto et al. teach of the following pharmaceutical composition of phenylephrine and the copolymer of methyl cellulose. Again, applicants are attempting to limit the instantly claimed composition claims with an intended use of the already known composition, as taught by Nakamoto et al. Although the prior art reference of Nakamoto et al. are silent to the effect of interfering with the isolation of the sympathomimetic amine as well as its conversion to other pharmacologically active forms, it well established in the art that pharmaceutical compositions contain binders, such as hydroxypropyl cellulose, ethyl cellulose and the copolymer of methyl acrylate, (see column 2, lines 18-43). Clearly, it would have been obvious to one having ordinary skill in the art at the time of the invention to employ the well known composition of a sympathomimetic amine, such as phenylephrine, along with pharmaceutically acceptable excipients namely, hydroxypropyl cellulose, ethyl cellulose and the copolymer of methyl acrylate. Note that composition claims are not deemed to be limited by “intended use”, see In re Hack 114 USPQ 161. In fact, it is noted that, “[T]he release [of] velocity of the medicament can be adjusted by proper selection of the ratio of the medicament or the ethyl cellulose or even the water soluble polymer. Since it is already known that the incorporation of binders or excipients, such as hydroxypropyl cellulose, ethyl cellulose and the copolymer of methyl acrylate, will control the rate of delivery of the active

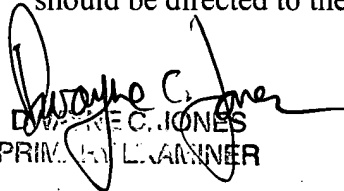
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compound, it would have been obvious to the skilled artisan to utilize these pharmaceutically acceptable excipients to modulate the activity of the active agents, specifically the sympathomimetic amines.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D.C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
DWAYNE C. JONES  
PRIMARY EXAMINER

Tech. Ctr. 1614

February 26, 2002